

DOCKET NO.: ISIS-4824

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PATENT

JUL 18 2006

REMARKS

Claims 30-40 are pending in the current case. Claims 30 and 40 have been amended. Claims 41 and 42 have been added. Support for claims 30 and 40-42 can be found throughout the specification, specifically in paragraph 0124. No new matter has been added. The Applicants submit that in view of the following comments that the case is in proper form for allowance.

In the Advisory Action, the Examiner states that neither explicit, implicit nor inherent support for a "single compartment capsule" was found in paragraph 0124. Applicants respectfully disagree. Paragraph 0124 states:

Capsules used for oral delivery may include formulations that are well known in the art. Further, multicompartment hard capsules... may also be used to formulate the compositions of the present invention.

Applicants submit that the existence of single compartment capsules (i.e., non-multicompartment capsules) is implicit and inherent by the distinction that capsules may be "multicompartment capsules." If only multicompartment capsules were known, such a modifier would not be required.

The test for sufficiency of support under the written description requirement was provided by the Court in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991), which stated, "Although [the applicant] does not have to describe exactly the subject matter claimed... the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted). The Court further stated that written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date. Applicants submit that those involved in formulation of pharmaceutical compositions have a high level of skill and education and that single compartment capsules are well known to those skilled in the art at the time of the filing of the application.

Furthermore, as detailed in the MPEP, the initial burden of proof in establishing whether the claims are supported by an adequate written description falls upon the Examiner. "The description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption"

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(MPEP 2163.04 and *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971)).

The Examiner has not provided sufficient evidence that one of skill in the art would not recognize that Applicants were in possession of the claimed invention at the time of filing. No evidence is presented to suggest that one of skill in the art, given the disclosure of the instant application, would not recognize Applicants to be in possession of the invention as claimed.

Rejections under 35 U.S.C. 103(a)

The Examiner has rejected claims 30-39 under 35 U.S.C. 103(a) as being unpatentable over WO99/60012 (Teng) in view of 5,672,359 (Digenis) and further in view of Muranishi for the reasons of record. The Applicants respectfully disagree with this rejection.

The Examiner has rejected claim 40 in view of the same references further in view of Urquhart. The Examiner states that the Teng does not teach a single dosage form wherein the two populations of carrier particles are released concurrently. The Examiner states that this deficiency is overcome by Urquhart who teaches a dosage form for delivering a single drug, two drugs or more, that are housed and separately dispensed. The claims have been amended to recite a single compartment capsule. This amendment is supported in paragraph 0124 which teaches non-multicompartment (i.e., single compartment) capsules. This is the opposite of what is taught by Urquhart. Therefore, the claims are not obvious in view of the prior art and the rejection is overcome.

FEES

The Commissioner is hereby entitled to charge the fee for a one (1) month extension fee in time for response (\$60.00) and the fee for a Request for Continued Examination (\$395), both small entity, to the Deposit Account 50-0252 referencing case ISIS-4824.

CONCLUSION

The Applicants submit that the application is now in proper form for allowance and respectfully request that the amendment be entered into the case after issuance of the final office action.

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If the Examiner believes that there are any outstanding issues remaining in the case, he is encouraged to contact the Agent for Applicant listed below to discuss the matter.

Respectfully submitted,



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